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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/506,430 02/17/00 GREEN

L 15542-002310

HM22/1018
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EXAMINER

LUKTON, D

ART UNIT

PAPER NUMBER

1653

16

DATE MAILED:

10/18/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/506,430

Applicant(s)

Green

Examiner

David Lukton

Art Unit

1653



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 10, 2001
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-42 is/are pending in the application.
- 4a) Of the above, claim(s) 23-27, 36-38, and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-22, 28-35, and 39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

Applicants' election of Group 8 (claims 18, 19, 21, 22, 28-35, 39, excluding compounds in which both of R' and R'' is an amide) is acknowledged. In addition, applicants have re-affirmed the previously elected specie (pGlu-Trp).

Claims 18-22, 28-35, 39 are examined in part. Claims 23-27, 36-38, 40-42 are withdrawn from consideration.

✱

This application contains sequence disclosures that are encompassed by the definitions for amino acid sequences set forth in 37 CFR 1.821. However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 with regard to the sequence disclosures.

See, for example, the peptide TAEKK (page 18).

Applicant is given the time period set in this letter within which to comply with the sequence rules, 37 CFR 1.821-1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response beyond the six month statutory period.

✱

Claims 18-22, 28-35, 39 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 18 recites the following:
"wherein R' is present if R" is present if R" is absent"
This contains an obvious error.
- Claim 18 is indefinite as to the process steps and endpoint. This rejection can be remedied by reciting that the compound is administered *for a time and under conditions effective to inhibit neovascularization*. Any of the following could be used:

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition comprising compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier for a time and under conditions effective to inhibit neovascularization.

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition for a time and under conditions effective to inhibit neovascularization, wherein said composition comprises a compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier.

A method of inhibiting neovascularization comprising administering to a subject in need thereof a pharmaceutical composition comprising compound of the formula R'Glu-Trp-R" in combination with a pharmaceutically acceptable carrier, wherein said method the composition is administered to the subject for a time and under conditions effective to inhibit neovascularization.

- In claim 20, the terms "Ac", "Suc", "Cpr", "But" may be used, but only if accompanied by the chemical names that they represent.

✱

The following is a quotation of 35 USC §103 which forms the basis for all obviousness

rejections set forth in the Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 18, 19, 21, 22, 28-35, 39, are rejected under 35 U.S.C. §103 as being unpatentable over Nishimura (USP 3,997,516) or Ryan (USP 4,191,53) in view of Rodgers (USP 5,716,935).

Nishimura discloses (e.g., col 10, line 44) a peptide that begins with the dipeptide pGlu-Trp, and further, that this peptide inhibits ACE. Similarly, Ryan discloses (e.g., col 5) peptide inhibitors of ACE that begin with the dipeptide pGlu-Trp. Neither reference discloses that inhibitors of ACE are also effective to inhibit neovascularization or angiogenesis. Rodgers discloses (col 3, line 5-10) that angiotensin stimulates neovascularization and angiogenesis. Rodgers does not disclose any of the peptides that are encompassed by the instant claims.

Accordingly, one of ordinary skill would have expected that an ACE inhibitor will inhibit

neovascularization and angiogenesis.

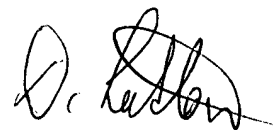
Thus, the claims are rendered obvious.

*

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



DAVID LUKTON
PATENT EXAMINER
GROUP 1800